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For: "ULTRASONIC DIAGNOSTIC IMAGING OF RESPONSE FREQUENCY
DIFFERING FROM TRANSMIT FREQUENCY"

Enclosed are:

- [X] Eight (8) sheets of drawings (informal).
- [X] Declaration and Power of Attorney.
- [] Information Disclosure Statement and PTO Form 1449.
- [X] One stamped, self-addressed postcard for the PTO Mail Room stamp.

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ULTRASONIC DIAGNOSTIC IMAGING OF RESPONSE FREQUENCY
DIFFERING FROM TRANSMIT FREQUENCY

This is a continuation-in-part of U.S. patent
5 application serial number 08/723,483, filed September
27, 1996 and entitled "ULTRASONIC DIAGNOSTIC IMAGING
WITH CONTRAST AGENTS."

This invention relates to ultrasonic diagnosis
and imaging of the body and, in particular, to new
10 methods and apparatus for ultrasonically imaging with
a response frequency which differs from the
transmitted frequency.

Ultrasonic diagnostic imaging systems have been
used to image the body with the enhancement of
15 ultrasonic contrast agents. Contrast agents are
substances which are biocompatible and exhibit
uniquely chosen acoustic properties which return
readily identifiable echo signals in response to
insonification. Contrast agents can have several
20 properties which enables them to enhance an
ultrasonic image. One is the nonlinear
characteristics of many contrast agents. Agents have
been produced which, when insonified by an ultrasonic
wave at one frequency, will exhibit resonance modes
25 which return energy at other frequencies, in
particular, harmonic frequencies. A harmonic
contrast agent, when insonified at a fundamental
frequency, will return echoes at the second, third,
fourth, and higher harmonics of that frequency.

30 It has been known for some time that tissue and
fluids also have inherent nonlinear properties.
Tissue and fluids will, even in the absence of a
contrast agent, develop and return their own non-
fundamental frequency echo response signals,
35 including signals at harmonics of the fundamental.

Muir and Carstensen explored these properties of water beginning in 1980, and Starritt et al. looked at these properties in human calf muscle and excised bovine liver.

5 While these non-fundamental frequency echo components of tissue and fluids are generally not as great in amplitude as the harmonic components returned by harmonic contrast agents, they do exhibit a number of characteristics which may be
10 advantageously used in ultrasonic imaging. One of us (M. Averkiou) has done extensive research into these properties in work described in his doctoral dissertation. In this exposition and other research, the present inventors have seen that the main lobe of
15 a harmonic beam is narrower than that of its fundamental, which they have found has implications for clutter reduction when imaging through narrow orifices such as the ribs. They have seen that the sidelobe levels of a harmonic beam are lower than the corresponding sidelobe levels of the fundamental beam, which they have found has implications for off-axis clutter reduction. They have also seen that harmonic returns from the near field are also relatively less than returning energy at the
20 fundamental frequency, which they have found has implications for near field clutter rejection. As will be seen, these properties may be exploited in the methods and constructed embodiments of the
25 present invention.

30 In accordance with the principles of the present invention, an ultrasonic imaging system and method are provided for imaging tissue and fluids from response frequencies which differ from the transmitted frequency, in particular echoes returned
35 from the tissue or fluids at a harmonic of a

transmitted fundamental frequency. The imaging system comprises a means for transmitting an ultrasonic wave at a fundamental frequency, means for receiving echoes at a harmonic frequency, and an 5 image processor for producing an ultrasonic image from the harmonic frequency echoes.

In a preferred embodiment of the present invention the transmitting and receiving means comprise a single ultrasonic probe. In accordance 10 with a further aspect of the present invention, the probe utilizes a broadband ultrasonic transducer for both transmission and reception.

In accordance with yet another aspect of the present invention, partially decorrelated components 15 of received harmonic echoes are produced and utilized to remove artifacts from the harmonic image, providing clearly defined images of tissue boundaries such as that of the endocardium. In a preferred embodiment the partially decorrelated components are produced by processing the harmonic echoes through 20 different passbands.

The methods of the present invention include the use of harmonic echoes to reduce near-field or multipath clutter in an ultrasonic image, such as 25 that produced when imaging through a narrow acoustic window such as the ribs. In accordance with yet a further aspect of the present invention, harmonic and fundamental echoes are blended in a common image to reduce clutter, image at appreciable depths, and 30 overcome the effects of depth-dependent attenuation.

In the drawings:

FIGURE 1 illustrates in block diagram form an ultrasonic diagnostic imaging system constructed in accordance with the principles of the present 35 invention;

FIGURES 2, 3, 4, and 5 illustrate certain properties of harmonic echoes which may be advantageously applied to ultrasonic imaging applications; and

5 FIGURES 6 and 7 illustrate passband characteristics used to explain the performance of the embodiment of FIGURE 1;

10 FIGURE 8 illustrates typical fundamental and harmonic frequency passbands of an embodiment of the present invention;

FIGURE 9 illustrates an FIR filter structure suitable for use in the embodiment of FIGURE 1;

15 FIGURE 10 illustrates in block diagram form a portion of a preferred embodiment of the present invention;

FIGURE 11 illustrates the operation of the normalization stages of the embodiment of FIGURE 10;

20 FIGURE 12 is a block diagram of one of the multiplier accumulators used in the filters of the embodiment of FIGURE 10;

FIGURE 13 illustrates typical fundamental and harmonic frequency passbands of the embodiment of FIGURE 10;

25 FIGURE 14 illustrates the blending of fundamental and harmonic signal components into one ultrasonic image; and

FIGURE 15 illustrates the passbands of a time varying filter used in the formation of blended images.

30 Referring first to FIGURE 1, an ultrasonic diagnostic imaging system constructed in accordance with the principles of the present invention is shown in block diagram form. A central controller 120 commands a transmit frequency control 117 to transmit 35 a desired transmit frequency band. The parameters of

the transmit frequency band, f_{tr} , are coupled to the transmit frequency control 117, which causes the transducer 112 of ultrasonic probe 110 to transmit ultrasonic waves in the fundamental frequency band.

5 In a constructed embodiment a band of frequencies located about a central frequency of 1.67 MHz is transmitted. This is lower than conventional transmitted imaging frequencies, which generally range from 2.5 MHz and above. However, use of a

10 typical transmit frequency of 3 or 5 MHz will produce harmonics at 6 and 10 MHz. Since higher frequencies are more greatly attenuated by passage through the body than lower frequencies, these higher frequency harmonics will experience significant attenuation as they return to the probe. This reduces the depth of penetration and image quality at greater imaging depths, although the harmonic signals, created as they are during the propagation of the transmitted wave through tissue, do not experience the

15 attenuation of a full round trip from the transducer as the fundamental signals do. To overcome this problem, the central transmit frequency in the illustrated embodiment is below 5 MHz, and preferably below 2.5 MHz, thereby producing lower frequency

20 harmonics that are less susceptible to depth dependent attenuation and enabling harmonic imaging at greater depths. A transmitted fundamental frequency of 1.67 MHz will produce second harmonic return signals at 3.34 MHz in the illustrated

25 embodiment. It will be understood, of course, that any ultrasonic frequency may be used, with due consideration of the desired depth of penetration and the sensitivity of the transducer and ultrasound system.

30

35 The array transducer 112 of the probe 110

transmits ultrasonic energy and receives echoes returned in response to this transmission. The response characteristic of the transducer can exhibit two passbands, one around the fundamental transmit frequency and another about a harmonic frequency in the received passband. For harmonic imaging, a broadband transducer having a passband encompassing both the transmitted fundamental and received harmonic passbands is preferred. The transducer may be manufactured and tuned to exhibit a response characteristic as shown in FIGURE 6, in which the lower hump 60 of the response characteristic is centered about the transmitted fundamental frequency f_t , and the upper hump 62 is centered about the received harmonic frequency f_r of the response passband. The transducer response characteristic of FIGURE 7 is preferred, however, as the single dominant characteristic 64 allows the probe to be suitable for both harmonic imaging and conventional broadband imaging. The characteristic 64 encompasses the transmitted fundamental frequency f_t , and also the harmonic receive passband bounded between frequencies f_L and f_c , and centered about frequency f_r . As discussed above, a low fundamental transmit frequency of 1.67 MHz will result in harmonic returning echo signals at a frequency of 3.34 MHz. A response characteristic 64 of approximately 2 MHz would be suitable for these fundamental and harmonic frequencies.

Tissue and cells in the body alter the transmitted fundamental frequency signals during propagation and the returned echoes contain harmonic components of the originally transmitted fundamental frequency. In FIGURE 1 these echoes are received by the transducer array 112, coupled through the T/R

switch 114 and digitized by analog to digital converters 115. The sampling frequency f_s of the A/D converters 115 is controlled by the central controller. The desired sampling rate dictated by
5 sampling theory is at least twice the highest frequency f_c of the received passband and, for the preceding exemplary frequencies, might be on the order of at least 8 MHz. Sampling rates higher than the minimum requirement are also desirable.

10 The echo signal samples from the individual transducer elements are delayed and summed by a beamformer 116 to form coherent echo signals. The digital coherent echo signals are then filtered by a digital filter 118. In this embodiment, the transmit
15 frequency f_t is not tied to the receiver, and hence the receiver is free to receive a band of frequencies which is different from the transmitted band. The digital filter 118 bandpass filters the signals in the passband bounded by frequencies f_L and f_c in
20 FIGURE 7, and can also shift the frequency band to a lower or baseband frequency range. The digital filter could be a filter with a 1 MHz passband and a center frequency of 3.34 MHz in the above example. A preferred digital filter is a series of multipliers
25 70-73 and accumulators 80-83 as shown in FIGURE 9. This arrangement is controlled by the central controller 120, which provides multiplier weights and decimation control which control the characteristics of the digital filter. Preferably the arrangement is controlled to operate as a finite impulse response
30 (FIR) filter, and performs both filtering and decimation. For example, only the first stage output 1 could be controlled to operate as a four tap FIR filter with a 4:1 decimation rate. Temporally
35 discrete echo samples S are applied to the multiplier

70 of the first stage. As the samples S are applied, they are multiplied by weights provided by the central controller 120. Each of these products is stored in the accumulator 80 until four such products
5 have been accumulated (added). An output signal is then produced at the first stage output 1. The output signal has been filtered by a four tap FIR filter since the accumulated total comprises four weighted samples. Since the time of four samples is required to accumulate the output signal, a 4:1
10 decimation rate is achieved. One output signal is produced for every four input samples. The accumulator is cleared and the process repeats. It is seen that the higher the decimation rate (the
15 longer the interval between output signals), the greater can be the effective tap number of the filter.

Alternatively, temporally separate samples are delayed by delay elements τ and applied to the four multipliers 70-73, multiplied, and accumulated in the accumulators 80-83. After each accumulator has accumulated two products, the four output signals are combined as a single output signal. This means that the filter is operating as an eight tap filter with a
20 2:1 decimation rate. With no decimation, the arrangement can be operated as a four tap FIR filter. The filter can also be operated by applying echo signals to all multipliers simultaneously and selectively time sequencing the weighting
25 coefficients. A whole range of filter characteristics are possible through programming of the weighting and decimation rates of the filter, under control of the central controller. The use of a digital filter provides the advantage of being
30 quickly and easily changed to provide a different
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filter characteristic. A digital filter can be programmed to pass received fundamental frequencies at one moment, and harmonic frequencies at the next. The digital filter can thus be operated to alternately produce images or lines of fundamental and harmonic digital signals, or lines of different alternating harmonics in a time-interleaved sequence simply by changing the filter coefficients during signal processing.

Returning to FIGURE 1, to image just a non-fundamental frequency, the digital filter 118 is controlled by the central controller 120 to pass echo signals at a harmonic frequency for processing, to the exclusion of the fundamental frequency. The harmonic echo signals from the tissue are detected and processed by either a B mode processor 37 or a contrast signal detector 128 for display as a two dimensional ultrasonic image on the display 50.

The filtered echo signals from the digital filter 118 are also coupled to a Doppler processor 130 for conventional Doppler processing to produce velocity and power Doppler signals. The outputs of these processors are coupled to a 3D image rendering processor 162 for the rendering of three dimensional images, which are stored in a 3D image memory 164. Three dimensional rendering may be performed as described in U.S. Pat. [appl. serial no. 08/638,710], and in U.S. Pats. 5,474,073 and 5,485,842, the latter two patents illustrating three dimensional power Doppler ultrasonic imaging techniques. The signals from the contrast signal detector 128, the processors 37 and 130, and the three dimensional image signals are coupled to a video processor 140 where they may be selected for two or three dimensional display on an image display 50 as dictated by user selection.

It has been found that harmonic imaging of tissue and blood can reduce near field clutter in the ultrasonic image. It is believed that the harmonic response effect in tissue is dependent upon the energy level of the transmitted waves. Near to an array transducer which is focused at a greater depth, transmitted wave components are unfocused and of insufficient energy to stimulate a detectable harmonic response in the near field tissue. But as the transmitted wave continues to penetrate the body, the higher intensity energy will give rise to the harmonic effect as the wave components begin to focus. While both near and far field regions will return a fundamental frequency response, clutter from these signals is eliminated by the passband of the digital filter 118, which is set to the harmonic frequency band. The harmonic response from the tissue is then detected and displayed, while the clutter from the near field fundamental response is eliminated from the displayed image.

FIGURES 2, 3, 4, and 5 illustrate some of the properties of harmonic return signals which can be utilized to advantage in ultrasonic imaging. It should be appreciated that several of these properties and their interactions are not yet fully and commonly understood among the scientific community, and are still the subject of research and discussion. FIGURE 2 illustrates the spatial response, and specifically the main lobe and sidelobes, of fundamental and harmonic signals received by a transducer array 112. In this illustration the array is directed to image an area of the body behind the ribs, such as the heart, and the main lobe is seen to extend between ribs 10 and 10'. Overlying the ribs is a tissue interface 12, as

from a layer of fat between the skin and ribs. The FIGURE shows a main lobe of the fundamental signals FL1, and on either side of the main lobe are sidelobes FL2 and FL3. The FIGURE also shows the
5 main lobe HL1 of a harmonic of the fundamental frequency, and sidelobes HL2 and HL3 of the harmonic main lobe.

In this example it is seen that the main lobe of the fundamental echoes is wide enough to encompass
10 portions of the ribs 10,10'. Accordingly, acoustic energy at the fundamental can be reflected back toward the transducer 112 as indicated by the arrow 9. While some of the energy of this reflection may travel back to and be received directly by the
15 transducer, in this example some of the reflected energy is reflected a second time by the tissue interface 12, as indicated by arrow 9'. This second reflection of energy reaches the other rib 10', where it is reflected a second time as shown by arrow 9"
20 and travels back to and is received by the transducer 112.

Since the intent of this imaging procedure is to image the heart behind the ribs, these echoes reflected by the ribs are unwanted artifacts which contaminate the ultrasonic image. Unwanted echoes which are reflected a number of times before reaching the transducer, such as those following the paths of arrows 9,9',9", are referred to as multipath artifacts. Together, these artifacts are referred to
25 as image "clutter", which clouds the near field and in some cases all of the image. This near field haze or clutter can obscure structure which may be of interest near the transducer. Moreover, the multipath artifacts can be reproduced in the image at
30 greater depths due to the lengthy multiple paths
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traveled by these artifacts, and can clutter and obscure regions of interest at greater depths of field.

But when only the harmonic return signals are used to produce the ultrasonic image, this clutter from the fundamental frequencies is filtered out and eliminated. The main lobe HL1 of the received harmonic echoes is narrower than that of the fundamental, and in this example passes between the ribs 10,10' without intersecting them. There are no harmonic returns from the ribs, and no multipath artifacts from the ribs. Thus, the harmonic image will be distinctly less cluttered and hazy than the fundamental image, particularly in the near field in this example.

FIGURE 3 shows a second example in which the main lobes of both the fundamental and harmonic returns do not intersect the ribs, and the problem discussed in FIGURE 2 does not arise. But in this example the ribs 10, 10' are closer to the skin surface and the transducer 112. While the main lobes do not intersect the ribs, the sidelobes FL2 of the fundamental do reach the ribs, allowing sidelobe energy to be reflected back to the transducer as shown by reflection path 9. Again, this will produce clutter in the fundamental image. But the smaller and narrower sidelobes HL2 of the received harmonic energy do not reach the ribs. Again, the harmonic image will exhibit reduced clutter as compared to the fundamental image.

FIGURE 4 illustrates the fundamental and harmonic beam patterns in a perspective which is across the lobes of FIGURES 2 and 3, that is, across the axis of the transducer. This drawing illustrates the relative amplitude responses of the fundamental

and second harmonic beam patterns. Illustrated are the dynamic response DRF between the main (FL1) and first sidelobe (FL2) of the fundamental component of the sound beam, and the dynamic response DRH between the main (HL1) and first sidelobe (HL2) of the second harmonic component. If responses due to the main lobes are considered desired signal responses, and responses due to the sidelobes are considered to be clutter or noise, the signal to noise ratio of the harmonic is greater than that of the fundamental. That is, there is relatively less sidelobe clutter in a harmonic image than in the corresponding fundamental image of the same transmission, or $DRH > DRF$.

FIGURE 5 illustrates another comparison of the properties of fundamental and harmonic signals, which is the relative amount of energy (in units of acoustic pressure P) emanating from increasing depths Z in the body at the fundamental and second harmonic frequencies. The curve denoted Fund. shows the buildup of propagated acoustic energy at the fundamental frequency. While the curve is seen to peak at the focus of the array transducer, it is seen that there is nonetheless an appreciable amount of fundamental energy at the shallower depths before the focal region. In comparison, there is comparatively much less energy, and a lesser buildup of energy, at the harmonic frequency propagated at these lesser depths of field. Hence, with less energy available for multipath reverberation and other aberrations, there is less near field clutter with harmonic imaging than with imaging the fundamental echo returns from the same transmission.

FIGURE 8 illustrates the bands of received signals and the digital filter of a typical FIGURE 1

embodiment of the present invention for a transmitted signal of four cycles of a 1.67 MHz acoustic wave. Transmitting multiple cycles narrows the bandwidth of the transmitted signal; the greater the number of 5 cycles, the narrower the bandwidth. In response to this transmission, the transducer 112 receives a fundamental signal in a bandwidth 90, which is seen to peak at the transmitted frequency of 1.67 MHz. As the fundamental frequency band rolls off, the 10 harmonic band 92 comes up, and is seen to exhibit a peak return at the harmonic frequency of 3.34 MHz. The received signals are applied to a digital filter with a passband characteristic 94, which is seen to be centered around the harmonic frequency of 3.34 15 MHz. As FIGURE 8 shows, this passband will substantially suppress signals at the fundamental frequency while passing the harmonic signals on to further processing and image formation. When imaging the heart in this manner, it has been found that the 20 harmonic response of the endocardial tissue of the heart is quite substantial, and harmonic tissue images of the heart show a clearly defined endocardial border.

Other signal processing techniques besides 25 filtering may be used to separate out harmonic signals from received echo information such as cancellation of the fundamental frequencies in a broadband signal, leaving only the harmonic frequencies. For example, U.S. Pat. [appl. SN 30 08/728,318] discloses a two pulse technique, whereby each scanline is insonified by consecutive fundamental frequency pulses of opposite phase in rapid succession. When the resultant echoes are received from the two pulses and combined on a 35 spatial basis, the fundamental frequencies will

cancel and the nonlinear or harmonic frequencies will remain. Thus, the harmonic frequencies are separated from the broadband echo signals without the need for a filter circuit.

5 FIGURE 10 shows a portion of a preferred embodiment of the present invention in block diagram form, from the beamformer output through to the image display. This embodiment not only produces harmonic images of tissue and blood flow, but also overcomes signal dropout deficiencies of conventional imaging systems which arise when imaging patients with difficult to image pathology. Additionally, this embodiment reduces an artifact of coherent ultrasound images known as speckle. In FIGURE 10, the signal and data lines connecting the blocks of the block diagram all represent multi-conductor digital data paths, as the processor of the illustrated embodiment is entirely digital. Scanline echo data from the beamformer 116 is applied in parallel to the two channels 30a,30b of the processor illustrated in

10 FIGURE 10, one of which is a high frequency channel and the other of which is a low frequency channel. Each channel of the processor has a normalization stage 32,132 which multiplies the scanline data by a

15 scale factor on a sample by sample basis to produce gain or attenuation that can vary with the depth of the body from which each sample returned. The scale factor for each channel is provided by normalization coefficients stored in or generated by coefficient

20 circuits 32,132, which in a preferred embodiment are digital memories. As the multiplying coefficients are changed along the sequence of scanline echoes, depth dependent gain or attenuation is produced.

25 The function of the normalization stages is two-fold. One is to compensate for a transducer aperture

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which expands with depth of scan. As signals from an increasing number of transducers are used with increasing depth, the magnitude of the summed beamformed signals will increase. This increase is offset by reduced gain (increased attenuation) in the normalization stage, in proportion to the rate at which channels are added to the beamforming process, so that the resultant echo sequence will be unaffected by the changing aperture.

The second function of the normalization stages is to equalize the nominal signal amplitudes of the two channels 30a,30b. The nominal signal amplitudes of the passbands of the two channels are desirably the same, so that the original relative signal levels will be preserved after the passbands are summed to create the full harmonic passband. But ultrasound signals are subject to depth dependent attenuation which varies with frequency, higher frequencies being more greatly attenuated with depth than lower frequencies. To account for this depth dependent attenuation the coefficients for the normalization stages provide signal gain which increases with depth. Since the two channels employ different frequency passbands, the depth dependent gain of the two channels differs from one channel to the other. In particular, the rate of gain increase for the higher frequency passband channel is greater than that of the lower frequency passband channel. This is illustrated in FIGURE 11, which, for purposes of illustration, shows the normalization gain characteristic of the higher frequency passband channel separated into two components. The depth dependent characteristic 200 offsets the effect of an increasing aperture in the channel, and the depth dependent characteristic 202 compensates for depth

dependent signal attenuation. The low frequency passband channel may also have a depth dependent gain characteristic but with a different characteristic 202 for the different rate of attenuation of the lower frequencies. The high frequency passband channel has a similar but more rapidly increasing depth dependent gain characteristic to account for the more rapid rate of attenuation of the higher frequencies. Each depth dependent gain characteristic 202 is chosen to offset the effect of depth dependent gain for the particular frequency passband employed by that channel.

In a preferred embodiment the coefficients of the coefficient circuits apply a gain or attenuation characteristic which is a combination of the two characteristics 200,202. Preferably, the coefficient memories 32,132 store multiple combined gain curves which are changed with memory addressing to match scanhead characteristics or the type of signals being processed (2D or Doppler). The rate of gain change may be controlled by the rate at which the coefficients are changed for the multiplier of each normalization stage 30,130.

The normalized echo signals in each channel are coupled to quadrature bandpass filters (QBFs) in each channel. The quadrature bandpass filters provide three functions: band limiting the RF scanline data, producing in-phase and quadrature pairs of scanline data, and decimating the digital sample rate. Each QBP comprises two separate filters, one producing in-phase samples (I) and the other producing quadrature samples (Q), with each filter being formed by a plurality of multiplier-accumulators (MACs) implementing an FIR filter. One such MAC is shown in FIGURE 12. As an echo sample of the scanline data is

applied to one input of a digital multiplier 210 a coefficient is applied to the other multiplier input. The product of the echo sample and the weighting coefficient is stored in an accumulator 212 where it may be accumulated with previous products. Other MACs receive the echo samples at different phases and likewise accumulate weighted echo samples. The accumulated outputs of several MACs can be combined, and the final accumulated product comprises filtered echo data. The rate at which accumulated outputs are taken sets the decimation rate of the filter. The length of the filter is a product of the decimation rate and the number of MACs used to form the filter, which determine the number of incoming echo samples used to produce the accumulated output signal. The filter characteristic is determined by the values of the multiplying coefficients. Different sets of coefficients for different filter functions are stored in coefficient memories 38,138, which are coupled to apply selected coefficients to the multipliers of the MACs. The MACs effectively convolve the received echo signals with sine and cosine representative coefficients, producing output samples which are in a quadrature relationship.

The coefficients for the MACs which form the I filter implement a sine function, while the coefficients for the Q filter implement a cosine function. For bandpass filtering, the coefficients of the active QBPs additionally implement a low pass filter function that is frequency shifted to form, in combination with the sine (for I) and cosine (for Q) functions, a bandpass filter for the quadrature samples. In the instant example, QBP₁ in channel 30a is producing I and Q samples of the scanline data in a first, low frequency passband, and QBP₂ in channel

30b is producing I and Q samples of the scanline data in a second, higher frequency passband. Thus, the spectrum of the original broadband echo signals is divided into a high frequency band and a low
5 frequency band. To complete the dropout and speckle reduction process, the echo data in the passband produced by QBP₁ of channel 30a is detected by a detector 40₁ and the detected signals are coupled to one input of a summer 48. In a preferred embodiment
10 detection is performed digitally by implementing the algorithm $(I^2+Q^2)^{1/2}$. The echo data in the complementary passband produced by QBP₂ of channel 30b is detected by a detector 40₂ and these detected signals are coupled to a second input of the summer
15 48. When the signals of the two passbands are combined by the summer 48, the decorrelated signal dropout and speckle effects of the two passbands will at least partially cancel, reducing the signal dropout and speckle artifacts in the 2D image created
20 from the signals.

Following the detector in each subchannel is a gain stage formed by multipliers 44₁, 44₂ which receive weighting coefficients from coefficient memories 42₁, 42₂. The purpose of this gain stage is to
25 partition the balance of analog and digital gains in the ultrasound system for optimal system performance. Some of the gains in the echo signal path may be automatically implemented by the ultrasound system, while others, such as manual gain control and TGC
30 gain, may be controlled by the user. The system partitions these gains so that the analog gains preceding the ADCs (analog to digital converters) of the beamformer are adjusted optimally for the dynamic input range of the ADCs. The digital gain is
35 adjusted to optimize the brightness of the image.

The two gains together implement gain control changes effected by the user.

In the preferred embodiment the gain imparted to the scanline signals by the multipliers 44₁,44₂ is selected in concert with the gain of the preceding normalization stage 34,134 in the channel. The gain of each normalization stage is chosen to prevent the attainment of saturation levels in the QBP's, as may occur when strong signals from contrast agents or harmonic imaging are being received. To prevent saturation levels the maximum gain of the normalization stage is controlled, and any reduction imposed by reason of this control is restored by the gain of the succeeding multiplier 44₁,44₂.

The gain function provided by these multipliers could be performed anywhere along the digital signal processing path. It could be implemented by changing the slope of the compression curves discussed below. It could also, for instance, be performed in conjunction with the gains applied by the normalization stages. This latter implementation, however, would eliminate the ability to effect the saturation control discussed above. The present inventors have found implementation of this gain function to be eased when provided after detection, and in the preferred embodiment by use of a multiplier after detection.

The signals produced by the gain stages 44₁,44₂ generally exhibit a greater dynamic range than may be accommodated by the display 50. Consequently, the scanline signals of the multipliers are compressed to a suitable dynamic range by lookup tables. Generally the compression is logarithmic, as indicated by log compression processors 46₁,46₂. The output of each lookup table is proportional to the log of the signal

input value. These lookup table are programmable so as to provide the ability to vary the compression curves, and the brightness and dynamic range of the scanline signals sent on for display.

5 The present inventors have found that the use of log compression to scale the echo signals can affect low level signals near the baseline (black) level of the signal dynamic range by exacerbating the degree and the number of echoes with components at the black
10 level, a manifestation of the destructive interference arising from the speckle effect of the coherent ultrasonic energy. When the echo signals are displayed, many of them will be at the black level, and appear in the image to have been
15 undetected or dropped out. The embodiment of FIGURE 10 reduces this problem by producing separate, partially decorrelated versions of the echo signals in the two channels 30a,30b. This embodiment partially decorrelates the echo signal versions by
20 separating the echo signal components into two different passbands as shown in FIGURE 13. The two passbands can be completely separated or, as shown in this example, overlapping. In this example, the lower passband 300a is centered about a frequency of
25 3.1 MHz, and the higher passband 300b is centered about a frequency of 3.3 MHz, a center frequency separation of only 200 kHz. Even this small degree of separation has been found sufficient to decorrelate the signal components of the two
30 passbands sufficiently such that black level signal dropout in one passband will frequently not align in frequency with its corresponding component in the other passband. Consequently, when these decorrelated replicas of the same echo signal are
35 combined by the summer 48, the signal dropout and

speckle artifacts will be markedly reduced. This is especially significant when trying to image fine structures at deep depths in the body, such as the endocardium. A harmonic image of the endocardium is significantly improved by the artifact elimination effects of the embodiment of FIGURE 10.

As discussed previously the signal gain of the two passbands 300a,300b of FIGURE 13 can be matched to preserve the original signal levels after summation. However, in a preferred embodiment, the lower frequency passband is processed with less dynamic range than the higher frequency passband as shown in FIGURE 13. This has the effect of suppressing the fundamental frequency contributions of the lower frequency passband (which contains more fundamental frequency components than the higher frequency band.) This is accomplished as a component of different compression characteristics in the log compression processors 46₁,46₂, or elsewhere in the channels 30a,30b subsequent to the separation of the broadband signal into separate passbands.

The processed echo signals at the output of the summer 48 are coupled to a lowpass filter 52. This lowpass filter, like the QBPs, is formed by combinations of multiplier-accumulators with variable coefficients, arranged to implement an FIR filter, to control the filter characteristic. The lowpass filter provides two functions. One is to eliminate sampling frequency and other unwanted high frequency components from the processed echo signals. A second function is to match the scanline data rate to the vertical line density of the display 50, so as to prevent aliasing in the displayed image. The FIR filter performs this function by selectively decimating or interpolating the scanline data. The

filtered echo signals are then stored in an image memory 54. If the scanlines have not yet been scan converted, that is, they have r,θ coordinates, the scanlines are scan converted to rectilinear
5 coordinates by a scan converter and greyscale mapping processor 56. If scan conversion has been performed earlier in the process, or is not needed for the image data, the processor 56 may simply convert the echo data to the desired greyscale map by a lookup
10 table process. The image data may then be stored in a final image memory or sent to a video display driver (not shown) for conversion to display signals suitable for driving the display 50.

It will be appreciated that, due to the
15 advantage of the quick programmability of a digital filter, the processing described above can be performed in an embodiment which utilizes a single one of the channels 30a, 30b to process the echo data from a scanline twice to alternately produce a line
20 of signals for each of the two passbands in a time-interleaved fashion. However, the use of two parallel channels affords twice the processing speed, enabling harmonic images to be produced in real time and at twice the frame rate of a time multiplexed
25 embodiment.

Harmonic images produced from high frequency signals can suffer from depth dependent attenuation as the echo signals return from increasing depths in the body. Lower frequency fundamental signals may
30 experience less attenuation, and hence in some cases may exhibit better signal to noise ratios at greater depths. The embodiment of FIGURE 14 takes advantage of this characteristic by blending fundamental and harmonic image data in one image. It is possible,
35 for instance, to create a normal tissue image of the

heart from fundamental frequencies, and overlay the fundamental frequency tissue image with a harmonic tissue image of the heart to better define the endocardial border in the composite image. The two 5 images, one from fundamental frequency components and another from harmonic frequency components, may be formed by alternately switching the digital filter 118 between fundamental and harmonic frequencies to separately assemble fundamental and harmonic images, 10 or by employing the two parallel filters of FIGURE 10 with two passbands, one set to pass fundamental frequencies and the other set to pass harmonic frequencies. In FIGURE 14, the filter of channel 30a is set to pass fundamental signal frequencies, and 15 echo signals passed by this channel are stored in a fundamental image memory 182. Correspondingly, harmonic signal frequencies are passed by channel 30b and stored in a harmonic image memory. The fundamental and harmonic images are then blended 20 together by a proportionate combiner 190, under control of a blend control 192. The blend control 192 may automatically implement a pre-programmed blending algorithm, or one directed by the user. For example, the proportionate combiner 190 may create a 25 blended image which uses only echo data from the harmonic image at shallow depths, then combines echo data from both image at intermediate depths, and finally only uses echo data of the fundamental image at deep depths. This combines the reduced clutter 30 benefit of harmonic echo data at shallow depths and the greater penetration and signal to noise ratio of fundamental echoes received from deeper depths, while affording a smooth transition from one type of data to the other at intermediate depths. Other combining 35 algorithms are also possible, such as simply

switching from one type of data to another at a predetermined depth, or outlining a region of the image to be displayed with one type of data while the remainder of the image is displayed using the other type of data.

5 It is also possible to employ the two parallel filters and blend the components together before image formation, thereby adding a controllable component of the harmonic echo signals to the fundamental frequency signals to enhance the resultant image. Such an embodiment could eliminate 10 the need for separate fundamental and harmonic image memories and would process the signal components directly to a blended image memory.

15 A third technique for producing blended images is to receive each scanline of the image through a depth-dependent, time varying filter. Such filters are well known for improving the signal to noise ratio of received echo signals in the presence of 20 depth dependent attenuation as shown, for instance, in U.S. Pat. 4,016,750. For the production of blended fundamental and harmonic images, the passband 210 of a time varying filter is initially set to pass harmonic frequencies f_h , as shown in FIGURE 15, as 25 echo signals begin to be received from shallow depths. When it becomes desirable to begin supplementing the image with fundamental signal components at deeper depths, the passband 210 undergoes a transition to lower frequencies, 30 eventually moving to the fundamental frequencies f_f as shown by passband 212 in FIGURE 15. In the case of a digital filter such as that shown in FIGURE 9, the change in passband frequencies is effected by changing the filter coefficients with time. As the 35 filter undergoes this transition, the passband passes

fewer harmonic frequencies and greater fundamental frequencies until eventually, if desired, the passband is passing only fundamental frequencies at the maximum image depth. By receiving each scanline through such a time varying filter, each line in the resultant image can comprise harmonic frequencies in the near field (shallow depths), fundamental frequencies in the far field (deepest depths), and a blend of the two in between.

A fourth technique for producing blended images is to transmit and receive twice along each scanline. One transmission is at a fundamental frequency and is followed by reception of echoes at a harmonic frequency. Another transmission is at a fundamental frequency, followed by reception at the fundamental frequency. The two fundamental transmission frequencies may be the same or, if desired, may be different fundamental frequencies. The harmonic and fundamental echoes are then combined along the scanline in the desired proportions to form a blended scanline, and an image field of such scanlines are produced to form a blended image.

Harmonic tissue images of moving tissue can also be formed by processing the received harmonic tissue echo signals with the processor described in U.S. Patent [application 08/655,394], entitled MEDICAL ULTRASONIC POWER MOTION IMAGING.

Thus, the present invention encompasses an ultrasonic imaging system for imaging the nonlinear response of tissue and fluids of the body to ultrasound by transmitting a fundamental frequency signal, receiving an echo signal from the tissue at a non-fundamental, preferably harmonic, frequency, detecting the non-fundamental frequency echo signals, and forming an image of the tissue and fluids from

the non-fundamental frequency echo signals. As used herein the term harmonic also refers to harmonic frequencies of higher order than the second harmonic and to subharmonics, as the principles described herein are equally applicable to higher order and subharmonic frequencies.

WHAT IS CLAIMED IS:

1. An ultrasonic diagnostic imaging system for imaging the harmonic response of structure inside a body, comprising:

5 means for transmitting ultrasonic energy into the body at a fundamental frequency;

means, responsive to said transmitted ultrasonic energy, for receiving ultrasonic echo signals at a 10 harmonic of said fundamental frequency; and

means for producing an ultrasonic image from said harmonic echo signals.

2. The ultrasonic diagnostic imaging system of 15 Claim 1, wherein said means for transmitting and said means for receiving comprise an ultrasonic transducer probe.

20 3. The ultrasonic diagnostic imaging system of Claim 2, wherein said ultrasonic transducer probe comprises a plurality of transducer elements for transmitting ultrasonic energy at a fundamental frequency and for receiving ultrasonic echo signals at a harmonic of said fundamental frequency.

25 4. The ultrasonic diagnostic imaging system of Claim 3, wherein said transducer elements exhibit a response characteristic which encompasses both said fundamental frequency and said harmonic of said fundamental frequency.

30 5. The ultrasonic diagnostic imaging system of Claim 1, wherein said means for receiving ultrasonic echo signals at a harmonic of said fundamental frequency comprises a filter defining a passband

which includes said harmonic frequency to the exclusion of said fundamental frequency.

5 6. The ultrasonic diagnostic imaging system of
Claim 5, wherein said filter comprises a programmable
digital filter.

10 7. The ultrasonic diagnostic imaging system of
Claim 1, wherein said means for producing an
ultrasonic image includes a B mode processor.

15 8. The ultrasonic diagnostic imaging system of
Claim 7, wherein said B mode processor includes an
amplitude detector for detecting the envelope of said
harmonic echo signals.

20 9. The ultrasonic diagnostic imaging system of
Claim 1, wherein said structure comprises naturally
occurring structure of the body.

25 10. The ultrasonic diagnostic imaging system of
Claim 9, wherein said naturally occurring structure
comprises tissue and cells of the body.

30 11. A method for producing an ultrasonic image
from the harmonic response of the interior of the
body comprising the steps of:
 transmitting ultrasonic energy into the body at
 a fundamental frequency;
 receiving ultrasonic echo signals at a harmonic
 of said fundamental frequency; and
 processing said harmonic echo signals to produce
 ultrasonic image display signals; and
 displaying said ultrasonic image display
 signals.

12. The method of Claim 11, wherein the steps
of transmitting and receiving comprise using an
ultrasonic probe with a transducer array to transmit
5 fundamental frequency ultrasonic energy and receive
harmonic echo signals.

13. The method of Claim 12, wherein the step of
using an ultrasonic probe comprises the step of
10 transmitting fundamental frequency ultrasonic energy
and receiving harmonic echo signals with the same
transducer elements.

14. The method of Claim 11, wherein the step of
receiving ultrasonic echo signals at a harmonic of
15 said fundamental frequency comprises passing received
ultrasonic echo signals through a filter which passes
signals at said harmonic of said fundamental
frequency to the exclusion of said fundamental
20 frequency.

15. The method of Claim 11, wherein said
processing step comprises B mode processing said
harmonic echo signals.

25 16. The method of Claim 15, wherein said step
of B mode processing includes the step of amplitude
detecting said harmonic echo signals.

30 17. An ultrasonic diagnostic imaging system for
producing an ultrasonic image of the harmonic
response of structure inside a body with reduced
artifacts, comprising:
35 means for transmitting ultrasonic energy into
the body at a fundamental frequency;

- means, responsive to said transmitted ultrasonic energy, for receiving ultrasonic echo signals at a harmonic of said fundamental frequency;
- 5 means for processing said harmonic ultrasonic echo signals to generate at least partially decorrelated replicas of said echo signals;
- means for combining said decorrelated replicas to produce artifact-reduced harmonic echo signals; and
- 10 means for utilizing said artifact-reduced harmonic echo signals to produce an ultrasonic image.
- 15 18. The ultrasonic diagnostic imaging system of Claim 17, wherein said artifacts comprise dropout artifacts.
- 20 19. The ultrasonic diagnostic imaging system of Claim 18, wherein said artifacts further comprise speckle artifacts.
- 25 20. The ultrasonic diagnostic imaging system of Claim 17, wherein said means for processing comprises a bandpass filter for separating components of said harmonic ultrasonic echo signals into two passbands having differing center frequencies.
- 30 21. The ultrasonic diagnostic imaging system of Claim 20, wherein said means for processing further comprises a detector for detecting harmonic ultrasonic echo signals in each of said passbands.
22. The ultrasonic diagnostic imaging system of Claim 21, wherein said means for processing further comprises a log compression processor for log

compressing said detected harmonic ultrasonic echo signals.

23. The ultrasonic diagnostic imaging system of
5 Claim 17, wherein said processing means comprises two parallel channels, each having an input coupled to receive harmonic ultrasonic echo signals and an output coupled to said combining means,

10 wherein each of said channels includes a bandpass filter having a filter characteristic different from that of the other channel.

15 24. The ultrasonic diagnostic imaging system of Claim 23, wherein said filter characteristic is the peak response frequency of the filter.

20 25. The ultrasonic diagnostic imaging system of Claim 23, wherein said filter characteristic is the center frequency of the filter.

25 26. The ultrasonic diagnostic imaging system of Claim 23, wherein each of said channels further includes a detector.

30 27. The ultrasonic diagnostic imaging system of Claim 26, wherein each of said channels further includes a log compression processor.

35 28. The ultrasonic diagnostic imaging system of Claim 17, wherein said processing means comprises means for separating said harmonic ultrasonic echo signals into two passbands of unequal dynamic range.

30 29. The ultrasonic diagnostic imaging system of Claim 28, wherein said two passbands comprise a low

frequency passband and a high frequency passband, and wherein the dynamic range of said low frequency passband is less than that of said high frequency passband.

5

30. The ultrasonic diagnostic imaging system of Claim 29, wherein said processing means further comprises means for mapping the dynamic range of each of said passbands differently.

10

31. A method for producing a harmonic ultrasonic image with reduced artifacts comprising the steps of:

15

transmitting ultrasonic energy at a fundamental frequency;

receiving ultrasonic echo signals at a harmonic of said fundamental frequency;

processing said harmonic echo signals to produce decorrelated replicas of said signals;

20

combining said decorrelated replicas to produce artifact reduced harmonic echo signals; and

utilizing said artifact reduced harmonic echo signals to produce an ultrasonic image.

25

32. The method of Claim 31, wherein the step of processing said harmonic echo signals comprises separating components of said harmonic echo signals into two different passbands.

30

33. The method of Claim 32, wherein the step of processing said harmonic echo signals comprises separating components of said harmonic echo signals into two different passbands of unequal dynamic range.

35

34. The method of Claim 33, wherein the step of
processing said harmonic echo signals comprises
separating components of said harmonic echo signals
into a high frequency passband of a given dynamic
range and a low frequency passband of a dynamic range
which is less than that of said given dynamic range.

35. An ultrasonic diagnostic imaging system for
producing a harmonic ultrasonic image of structure
inside a body, comprising:

means for transmitting ultrasonic energy into
the body at a fundamental frequency;
means, responsive to said transmitted ultrasonic
energy, for receiving ultrasonic echo signals at said
fundamental frequency and at a harmonic of said
fundamental frequency; and
an image processor which processes said received
fundamental frequency echo signals and harmonic
frequency echo signals to produce an ultrasonic image
formed of components of both said fundamental and
said harmonic echo signals.

36. The ultrasonic diagnostic imaging system of
Claim 35, wherein said receiving means includes means
for producing separated fundamental and harmonic
frequency echo signals.

37. The ultrasonic diagnostic imaging system of
Claim 36, wherein said receiving means includes a
filter for producing fundamental frequency echo
signals to the at least partial exclusion of harmonic
frequency echo signals, and for producing harmonic
frequency echo signals to the at least partial
exclusion of fundamental frequency echo signals.

38. The ultrasonic diagnostic imaging system of
Claim 35, wherein said image processor comprises
means for utilizing predominately harmonic echo
signals in the near field of said image, and
5 predominately fundamental frequency echo signals in
the far field of said image.

39. An ultrasonic diagnostic imaging system for
imaging the harmonic response of structure inside a
10 body which exhibits depth dependent attenuation of
ultrasonic energy, comprising:

means for transmitting ultrasonic energy into
the body at a fundamental frequency which is equal to
or less than 5 MHz;

15 means, responsive to said transmitted ultrasonic
energy, for receiving ultrasonic echo signals at a
harmonic of said fundamental frequency which is equal
to or less than 10 MHz; and

20 means for producing an ultrasonic image from
said harmonic echo signals.

40. The ultrasonic diagnostic imaging system of
Claim 39, wherein said transmitting means transmits
ultrasonic energy into the body at a fundamental
25 frequency which is equal to or less than 2.5 MHz; and

wherein said receiving means receives ultrasonic
echo signals at a harmonic of said fundamental
frequency which is equal to or less than 5 MHz.

30 41. The ultrasonic diagnostic imaging system of
Claim 39, wherein said transmitting means transmits
ultrasonic energy into the body at a fundamental
frequency which is less than 2 MHz; and

wherein said receiving means receives ultrasonic echo signals at a harmonic of said fundamental frequency which is less than 4 MHz.

5 42. The ultrasonic diagnostic imaging system of Claim 39, wherein said receiving means includes a programmable digital filter which is programmed to pass a band of said harmonic echo signals to the exclusion of said fundamental frequency.

10 43. An ultrasonic diagnostic imaging system for imaging the nonlinear response of tissue, comprising:
 a transmitter for transmitting ultrasonic energy into the body at a fundamental frequency;
15 a receiver, responsive to echoes returned from tissue following said ultrasonic energy transmission, for separating signals representing the nonlinear response of tissue to ultrasound; and
 an image processor for producing an ultrasonic image from said nonlinear response signals.

20 44. The ultrasonic diagnostic imaging system of Claim 43, wherein said receiver includes a filter circuit for separating signals representing the nonlinear response of tissue to ultrasound.

25 45. The ultrasonic diagnostic imaging system of Claim 43, wherein said receiver includes a signal processor, responsive to the reception of multiple echoes from the same spatial location in tissue, for combining said multiple echo signals to separate signals representing the nonlinear response of tissue to ultrasound.

30 46. The ultrasonic diagnostic imaging system of

Claim 43, wherein the the nonlinear response of tissue to ultrasound comprises a second or higher order harmonic of said fundamental frequency.

- 5 47. The ultrasonic diagnostic imaging system of Claim 43, wherein the the nonlinear response of tissue to ultrasound comprises a subharmonic of said fundamental frequency.

10

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ULTRASONIC DIAGNOSTIC IMAGING OF RESPONSE FREQUENCY
DIFFERING FROM TRANSMIT FREQUENCY

Abstract of the disclosure:

5

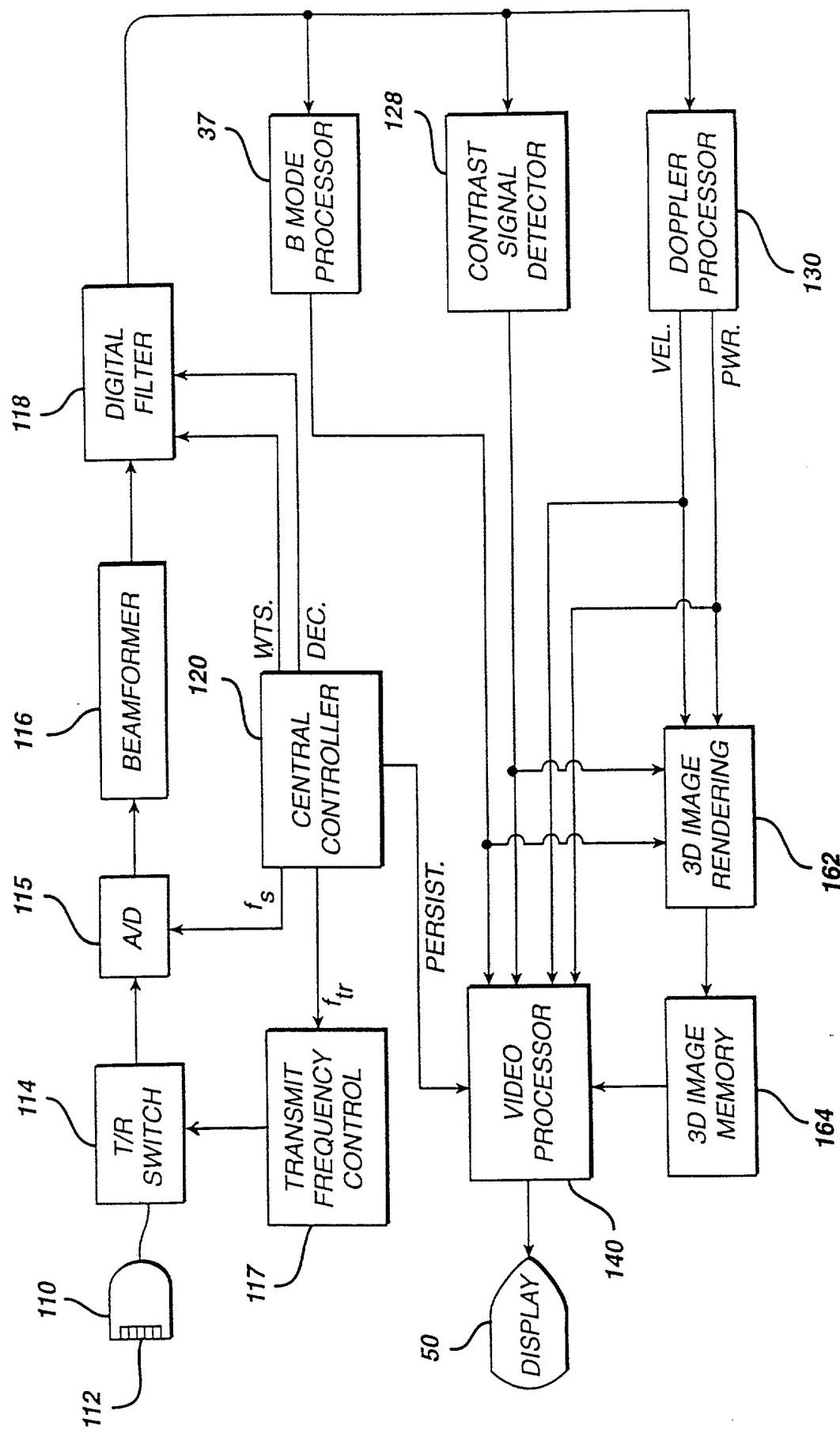
An ultrasonic diagnostic imaging system and methods are described which produces ultrasonic images from harmonic echo components of a transmitted fundamental frequency. Preferably, a programmable digital filter is used to pass harmonic echo components for image processing to the exclusion of fundamental frequency signals. In a preferred embodiment, artifacts are removed by producing decorrelated replicas of the harmonic signals, which are then combined and used for imaging. To produce an image in the presence of depth dependent attenuation of high frequency echo signals, both fundamental and harmonic echo signals are processed and used to produce an image blended from components of both fundamental and harmonic echo signals.

10

15

20

FIG. 1



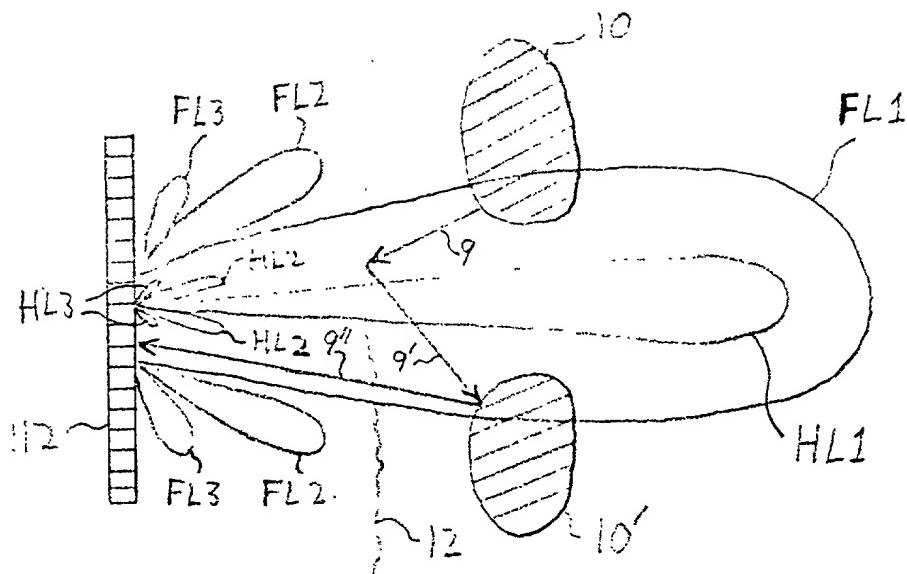


Fig. 2

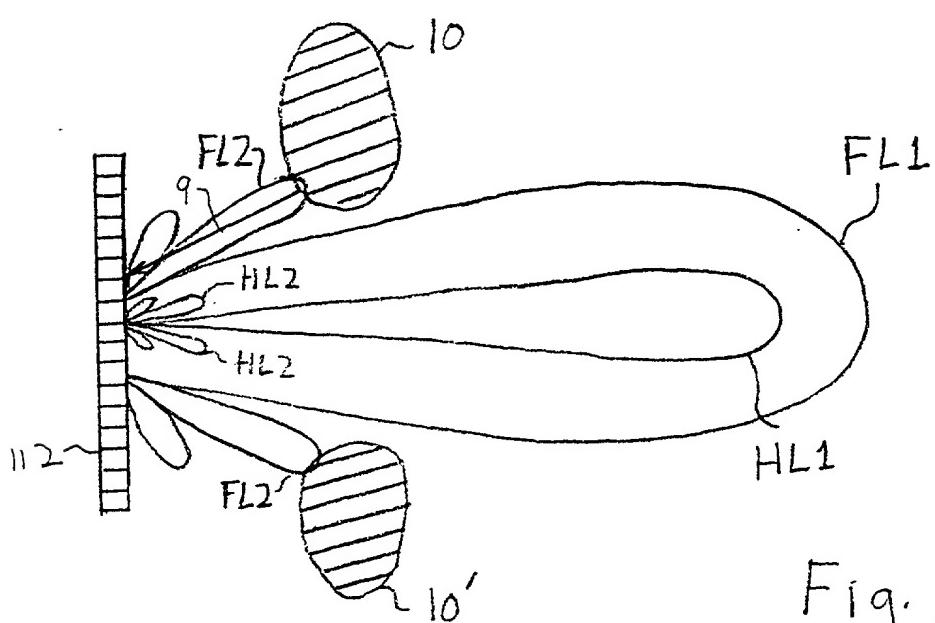


Fig. 3

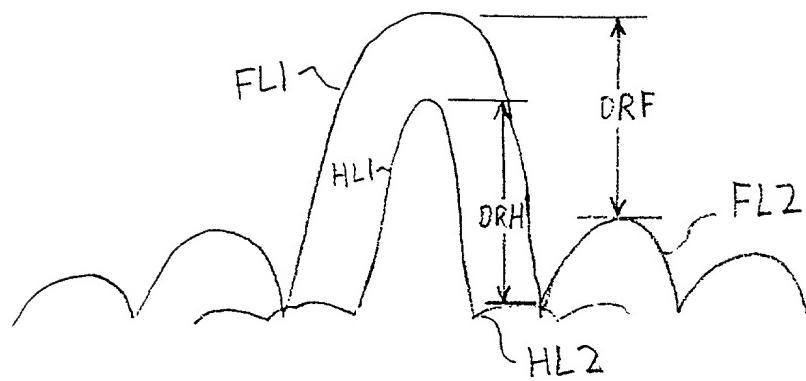


Fig. 4

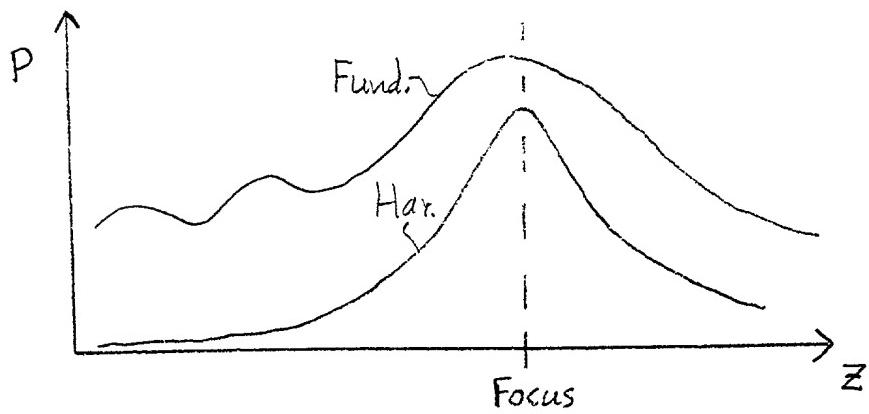
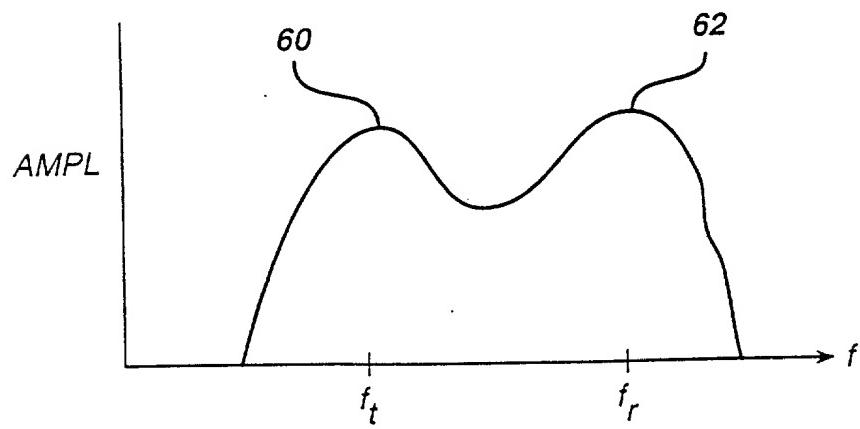


Fig. 5

**FIG. 6**

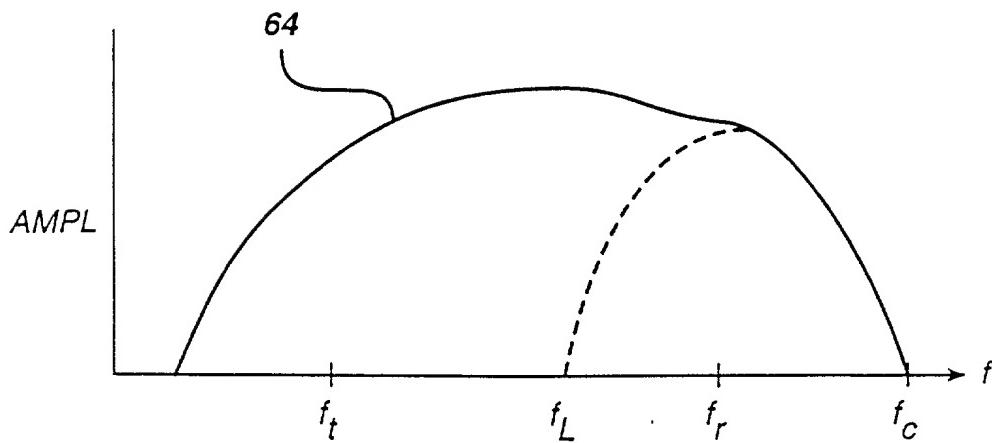


FIG. 7

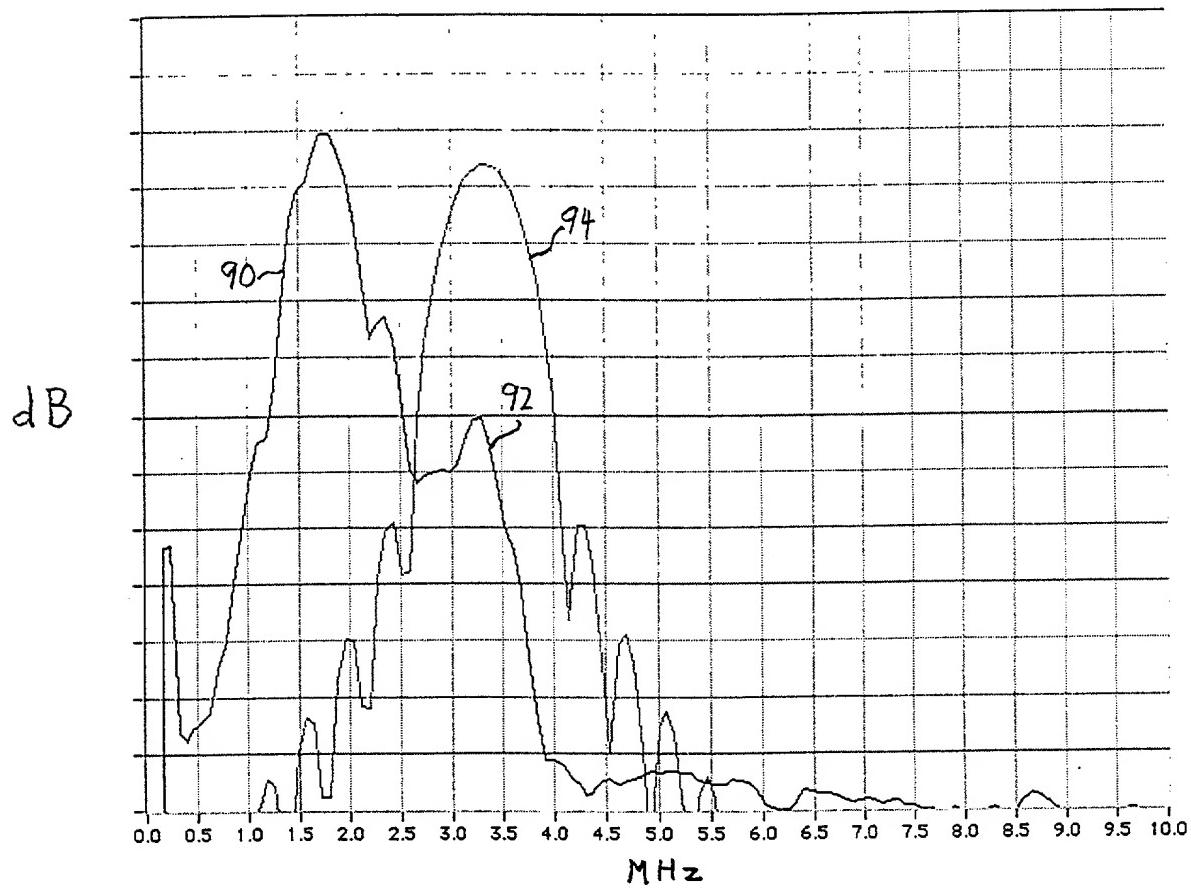


Fig. 8

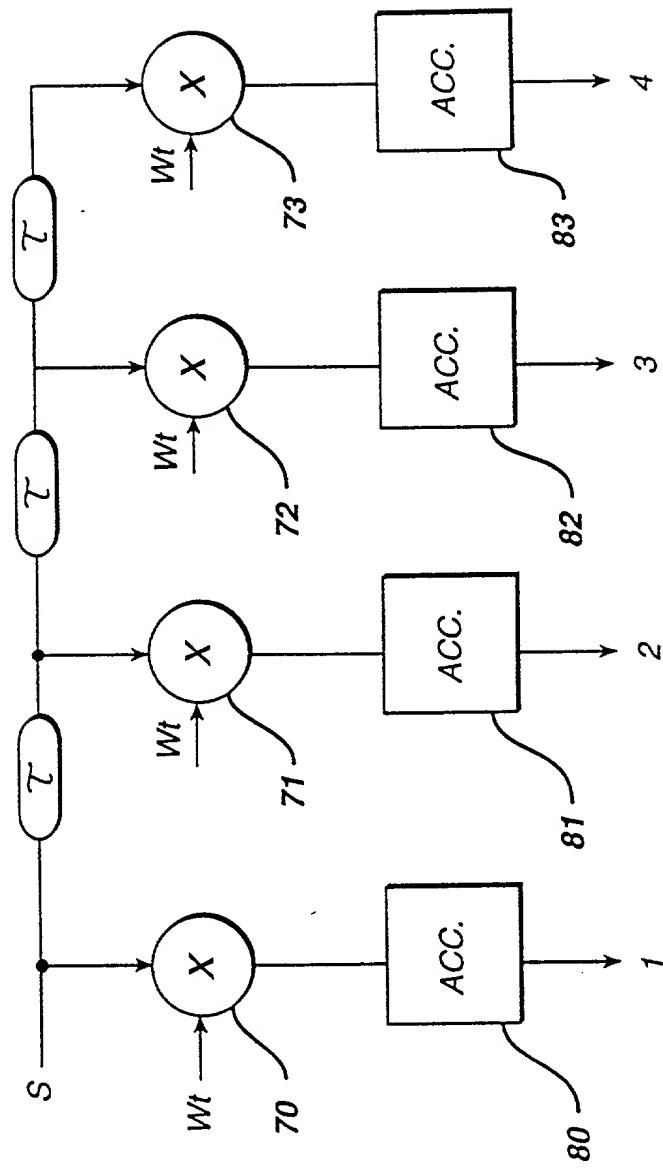
FIG. 9

FIG. 11

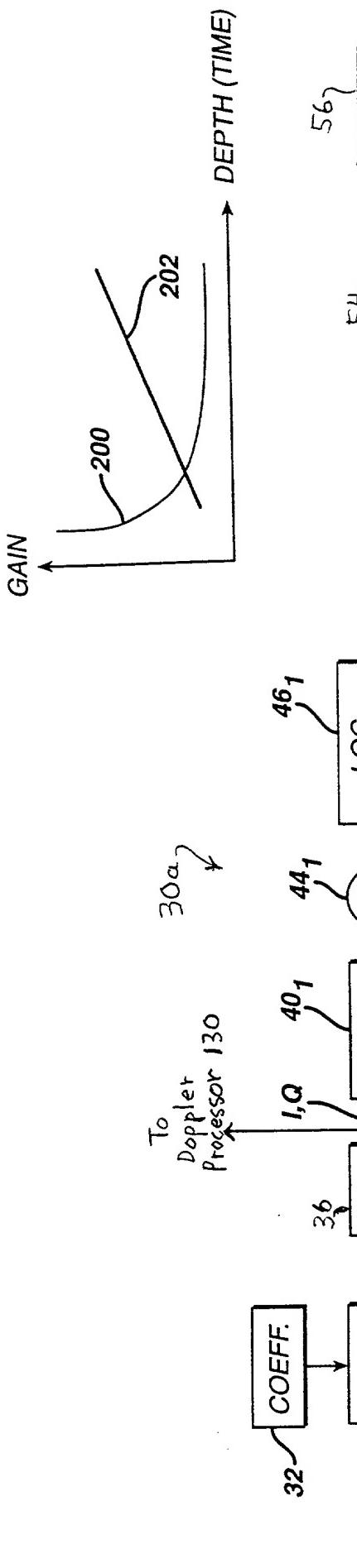


FIG. 10

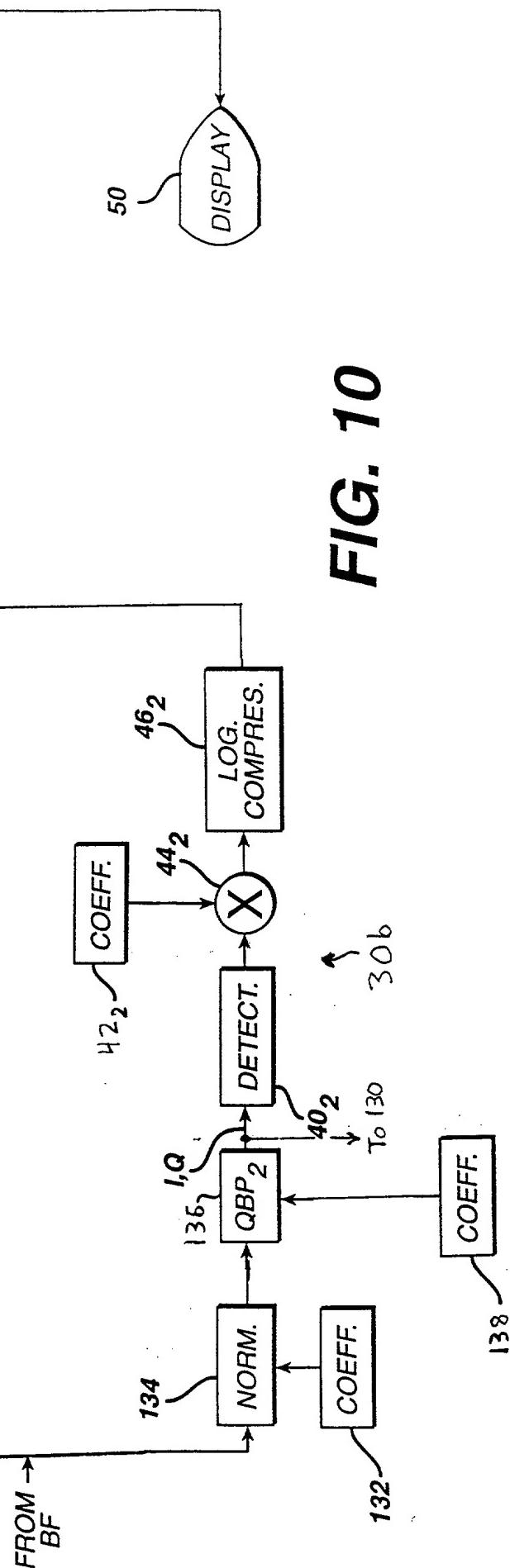
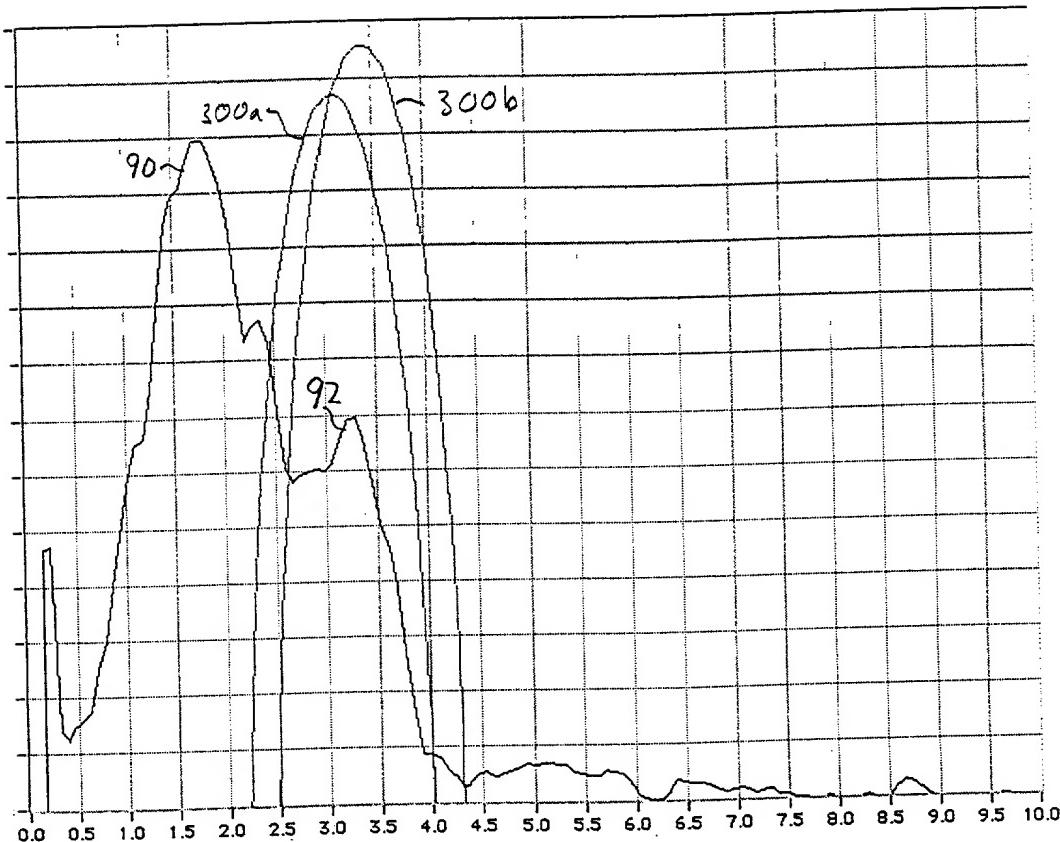
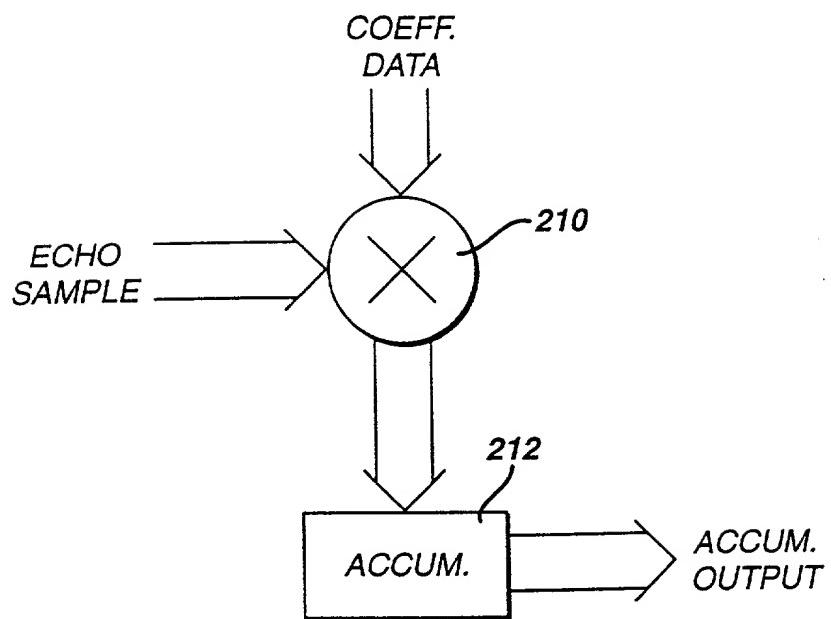


FIG. 12**FIG. 13**

Amp.

FIG. 15

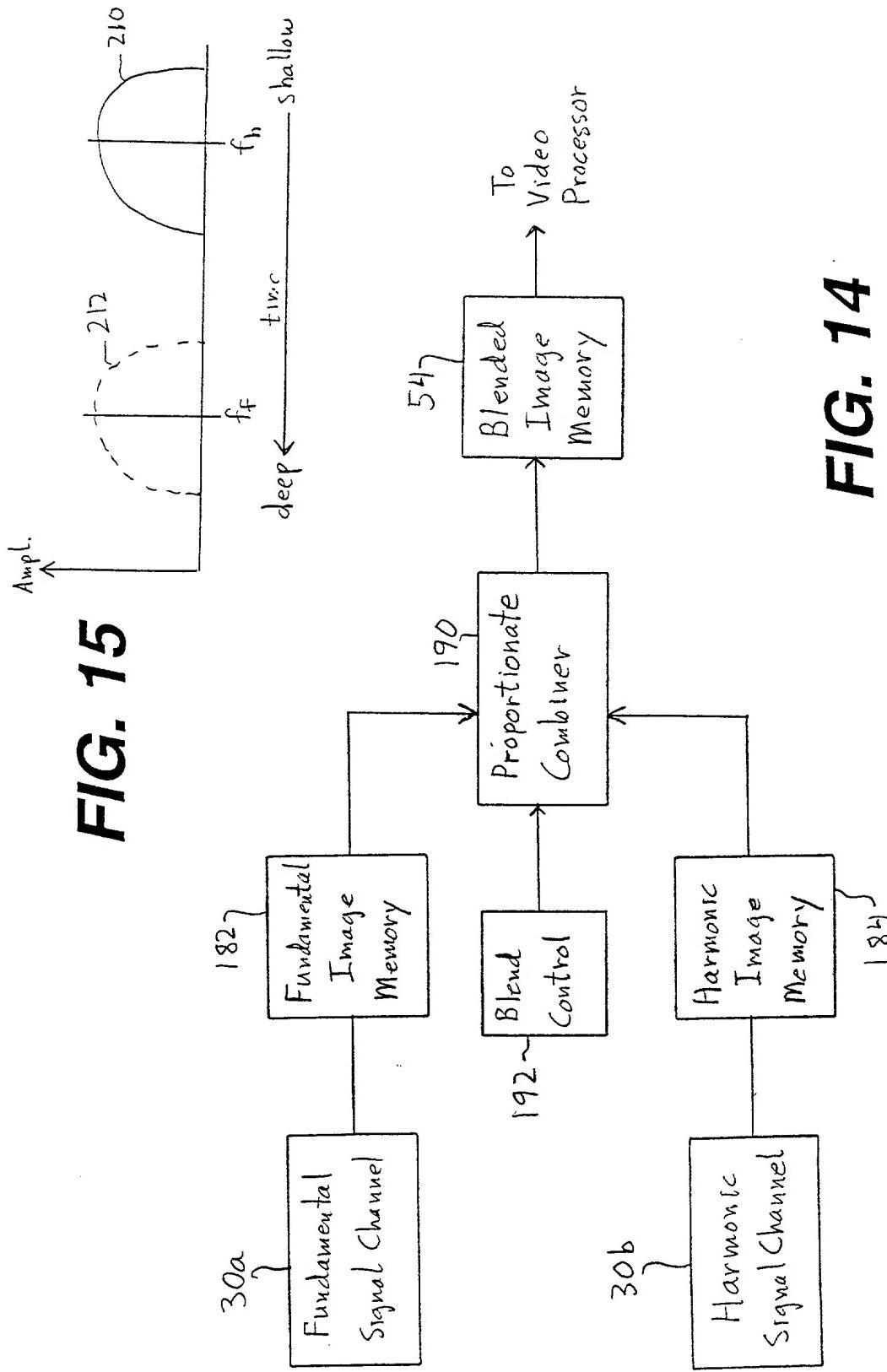


FIG. 14



DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

ULTRASONIC DIAGNOSTIC IMAGING OF RESPONSE FREQUENCY
DIFFERING FROM TRANSMIT FREQUENCY

the specification of which (check one)

[X] is attached hereto

[] was filed on _____ as Application
Serial No. _____.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>60/029,542</u> Application Serial No.	<u>11/08/96</u> Filing Date	<u>PROV.</u> Status
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<u>08/723,483</u> Application Serial No.	<u>09/27/96</u> Filing Date	<u>Pending</u> Status
---	--------------------------------	--------------------------

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: W. Brinton Yorks, Jr. (Reg. #28,923) and Frederick J. McKinnon (Reg. #28,240).

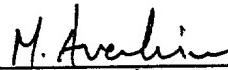
Address all telephone calls to W. Brinton Yorks, Jr. at telephone no. (425) 487-7152.

Address all correspondence to W. Brinton Yorks, Jr., ATL Ultrasound, Inc., 22100 Bothell Everett Highway, P.O. Box 3003, Bothell, Washington 98041-3003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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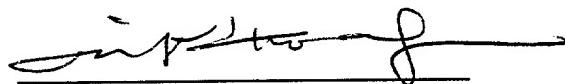
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